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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,730	02/10/2000	Merry R. Sherman	MVIEW.0050A	4303

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/531,991	VANCE ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claim 24 is pending in the application.

[2] Applicants' amendment to the claim filed January 15, 2004 is acknowledged. This listing of the claim replaces all prior versions and listings of the claim of the instant application.

[3] Applicant's arguments filed January 15, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

[4] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

[5] The rejection of claim 24 under 35 U.S.C. 103(a) as being unpatentable over Simon et al. (*JAMA* 245:2038-2043) in view of James et al. (*Br Med J (Clin Res Ed)* 290:854), Winearls et al. (*Lancet* 2(8517):1175-1178), Eschbach et al. (*N Engl J Med* 316:73-78), Lin et al. (US Patent 4,703,008), and Bayer et al. (*Ann Thorac Surg* 29:117-122, abstract) as set forth in item [6] of the Office action mailed July 10, 2003 is maintained for the reasons of record and the reasons stated below.

It is the examiner's position that the combined references of Simon et al., James et al., Winearls et al., Eschbach et al., Lin et al., and Bayer et al. render obvious the

claimed method for producing four or more units of blood for autologous transfusion. Applicants traverse the instant rejection by arguing that the requirements of 35 USC 103 are not met by the teachings of the cited references. In particular, applicants argue that methods of using EPO as described in the cited references were limited to the treatment of individuals exhibiting anemia and having low hematocrit levels. Applicants argue that at the time of the invention it was thought that EPO therapy would not be useful in normal individuals and that even the potential benefit of EPO therapy to correct anemia was doubted because of the alleged concern that erythropoietin inhibitors might block the effect of EPO. Applicants argue that their discovery "unexpectedly extinguished" such doubt. Applicants' argument is not found persuasive.

In this case, applicants assert that, at the time of the invention, EPO therapy would not be useful for treating individuals who are non-anemic and have a normal hematocrit level. Applicants' assertions appear to be based on the use of EPO treatment in the absence of iron supplementation in normal individuals (see page 4, lines 4-11 of the specification). Applicants' position appears to be that one of ordinary skill in the art would not expect to observe the same result in normal patients as that obtained by treatment with EPO/iron supplementation in anemic patients. It is acknowledged that the results of Winearls et al. and Eschbach et al. were obtained by studies of patients with renal disease. However, it is noted that Winearls et al. teach that even in patients with normal iron stores, the patients' response to EPO treatment was dependent upon additional iron supplied by their daily iron supplement. Therefore, based on this teaching, one of ordinary skill in the art would have recognized that

additional iron is required for response to EPO treatment – even in those patients with normal iron levels. Furthermore, while applicants suggest that one would have doubts as to whether EPO treatment alone would result in increased hematocrit, it is noted that there is no evidence of record that would suggest that, at the time of the invention, one of ordinary skill in the art would have doubted that EPO/iron supplementation would result in increased hematocrit. Based on the teachings of the cited references, one of ordinary skill in the art would have clearly been motivated to use iron supplementation prior to administration of EPO – even in patients with normal iron levels. Consequently, because a response to EPO/iron supplementation was obtained in patients having normal iron levels, one of ordinary skill in the art would have recognized that erythropoietin inhibitors cannot block the effect of EPO/iron supplementation – even in patients with normal iron levels.

Applicants argue Simon et al. do not teach or suggest EPO administration in connection with blood donation. Applicants argue James et al. teach nothing about blood donation and does not remedy the teachings of Simon et al. Applicants argue Winearls et al., Eschbach et al., Lin et al., and Bayer et al. do not teach administration of EPO to individuals with normal hematocrit and erythropoiesis-supportable iron levels for the purpose of blood donation. Applicants' argument is not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

1986). The examiner acknowledges that no single reference sufficiently renders obvious the claimed invention. In this case, it is the *combination* of references and the teachings provided therein (as set forth at pages 3-5 of the Office action mailed July 10, 2003) that clearly teach the claimed invention. Applicants acknowledge that Lin et al. suggest administration of EPO for blood transfusion and, combined with the additional teachings of the prior art, one would clearly be motivated and have an expectation of success for practicing the claimed invention.

Applicants argue that Bayer et al. contributes no meaningful information relating to a preferred number of blood units to be donated for autologous transfusion and therefore, does not provide motivation for collecting at least four units of blood. Applicants' argument is not found persuasive.

Contrary to applicants' argument, Bayer et al. do not teach away from collecting at least 4 units of blood. With the exception of coronary bypass surgery, Bayer et al. teach that all open-heart surgeries averaged 4.7 units of blood. Thus, one of ordinary skill in the art would have been motivated to collect at least 4.7 units of blood for an open-heart surgery other than coronary bypass surgery as this is the average required number of units of blood for this type of surgery.

Applicants argue that the motivation for the claimed invention could only have come from the specification, which constitutes an impermissible hindsight reasoning. Applicants' argument is not found persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the examiner has relied upon knowledge disclosed in publicly available references at the time of the invention. Thus, contrary to applicants' assertions, the motivation for practicing the claimed invention as set forth at page 6 of the Office action mailed July 10, 2003 is based on knowledge that was publicly available at the time of the invention and has not been gleaned for the specification.

Applicants argue that the cited references would not have provided a reasonable expectation of success for practicing the claimed invention. Applicants' argument is not found persuasive.

There is no evidence of record that supports applicants' argument that one of ordinary skill in the art would have expected the result obtained with EPO/iron supplementation in anemic patients would not apply to normal individuals as well, particularly in view of the teaching of Winearls et al., who demonstrated that even in patients with a normal iron level, the response to EPO was dependent upon external iron supplementation.

Conclusion

[6] Status of the claims:

- Claim 24 is pending.
- Claim 24 is rejected.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652